PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {100 ml Bottle label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox Ready-to-Use Suspension for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 35 mg/ml clavulanic acid as potassium clavulanate and 140 mg/ml amoxicillin as amoxicillin trihydrate.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, pigs, dogs and cats

6. INDICATION(S)

-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage and administration:

Shake well before use.

8.75 mg/kg bodyweight once daily for 3 to 5 days.

The following is intended as a guide:

8. WITHDRAWAL PERIOD

Withdrawal periods: Cattle: Meat - 42 days, Milk may only be taken at 60 hours (5th milking - if cows are milked twice daily). Pigs: Meat - 31 days.

Combined therapy: See package leaflet for details.

9. SPECIAL WARNING(S), IF NECESSARY

Contra-indications and warnings: In common with all other penicillins Synulox should not be administered to rabbits, guinea pigs, hamsters or gerbils.

Penicillins/cephalosporins may occasionally cause severe allergic reactions

For full information including adverse reactions and operator warnings see package leaflet.

WARNING: Water sensitive - use a dry syringe. Clavulanic acid is moisture sensitive. Read package leaflet for further information.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Once broached, use within 28 days. Discard unused material.

Keep the vial in the outer carton.

Once broached, use by:

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription

For animal treatment only.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Dublin 18
D18 T3Y1
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 60021/3021

17. MANUFACTURER'S BATCH NUMBER

Batch No:

PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGE {40 ml Bottle label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox Ready-to-Use Suspension for Injection

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Contains 35 mg/ml clavulanic acid as potassium clavulanate and 140 mg/ml amoxicillin as amoxicillin trihydrate.

3. BATCH NUMBER

Batch No:

4. EXPIRY DATE

Expiry date:

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

40 ml

6. ROUTE(S) OF ADMINISTRATION

Dosage and administration:

Shake well before use.

8.75 mg/kg bodyweight once daily for 3 to 5 days.

The following is intended as a guide:

7. WITHDRAWAL PERIOD

Withdrawal periods: Cattle: Meat - 42 days, Milk may only be taken at 60 hours (5th milking - if cows are milked twice daily). Pigs: Meat - 31 days.

Combined therapy: See package leaflet for details.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Outer label / carboard carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox Ready-to-Use Suspension for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 35 mg/ml clavulanic acid as potassium clavulanate and 140 mg/ml amoxicillin as amoxicillin trihydrate.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

40 ml
100 ml
12 x 40 ml
6 x 100 ml

5. TARGET SPECIES

Cattle, pigs, dogs and cats

6. INDICATION(S)

-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage and administration:

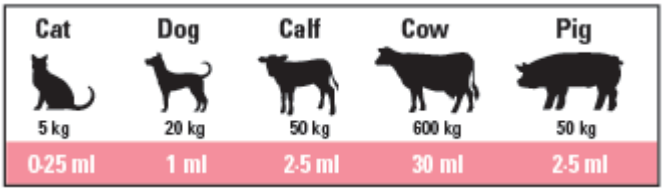
Shake well before use.

Dogs and cats: subcutaneous or intramuscular injection.

Cattle and pigs: intramuscular injection only .

8.75mg/kg bodyweight once daily for 3 to 5 days (equivalent to 1 ml/20 kg bodyweight daily).

The following is intended as a guide:



8. WITHDRAWAL PERIOD

Withdrawal periods: Cattle: Meat - 42 days, Milk may only be taken at 60 hours (5th milking - if cows are milked twice daily). Pigs: Meat - 31 days.

Combined therapy: See package leaflet for details.

9. SPECIAL WARNING(S), IF NECESSARY

For full information including adverse reactions see package leaflet.

Contra-indications and warnings: In common with all other penicillins Synulox should not be administered to rabbits, guinea pigs, hamsters or gerbils. Caution is advised in other very small herbivores.

User warnings: Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package leaflet for user warnings.

WARNING: Water sensitive - use a dry syringe. Clavulanic acid is moisture sensitive. Read package leaflet for further information.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Keep the vial in the outer carton.

Once broached, use within 28 days. Discard unused material.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription. For animal treatment only.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Dublin 18
D18 T3Y1
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 60021/3021

17. MANUFACTURER’S BATCH NUMBER

Batch No:

PACKAGE LEAFLET FOR:

Synulox Ready-to-Use Suspension for Injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Dublin 18
D18 T3Y1
Ireland

Manufacturer responsible for batch release:
Haupt Pharma Latina S.r.l.
SS 156 Km 47,600
06100 Borgo San Michele
Latina
Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox Ready-to-Use Suspension for Injection

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Synulox Ready-To-Use Injection is an off-white suspension containing 35 mg/ml clavulanic acid as Potassium clavulanate and 140 mg/ml amoxicillin as Amoxicillin trihydrate.

4. INDICATION(S)

Synulox Ready-To-Use Injection has a notably broad spectrum of bactericidal activity against the bacteria commonly found in cattle, pigs and small animals.

Mode of Action: Resistance to many antibiotics is caused by ß-lactamase enzymes which destroy the antibiotic before it can act on the bacteria themselves. The clavulanate in Synulox counter-acts this defence mechanism by inactivating the ß-lactamases, thus rendering the bacteria sensitive to amoxicillin's rapid bactericidal effect at concentrations readily attainable in the body.

In vitro Synulox is active against a wide range of clinically important bacteria including: Gram-positive: Staphylococci (including ß-lactamase producing strains), Streptococci, Corynebacteria, Clostridia, *Bacillus anthracis*, *Actinomyces bovis*, *Peptostreptococcus* spp.

Gram-negative: *Escherichia coli* (including ß-lactamase producing strains), Salmonellae (including ß-lactamase producing strains), *Bordetella bronchiseptica*, *Campylobacter* spp., Klebsiellae, *Proteus* spp., Pasteurellae, *Fusobacterium necrophorum*, Bacteroides (including ß-lactamase producing strains), *Haemophilus* spp., *Moraxella* spp., Actinobacillus pleuropneumoniae and *Actinobacillus lignieresi*.

Indications:

Cattle - respiratory infections, soft tissue infections (e.g. joint-ill, abscesses etc.) metritis and mastitis.

Pigs - respiratory bacterial infections in growing pigs, colibacillosis, periparturient infections in sows (e.g. mastitis-metritis- agalactia).

Dogs and cats - respiratory tract infections, urinary tract infections and skin and soft tissue infections (e.g. abscesses, pyoderma, anal sacculitis, gingivitis).

5. CONTRAINDICATIONS

In common with all other penicillins, Synulox should not be used orally or parenterally in rabbits, guinea pigs, hamsters or gerbils. Caution is advised in its use in any other very small herbivores.

The suspension is not suitable for intravenous or intrathecal administration. Great care should be taken to avoid contaminating the remaining contents of the vial with water (see Pharmaceutical Precautions).

6. ADVERSE REACTIONS

Very rarely, the use of the product may result in pain on injection and/or local tissue reactions.

Allergic reactions (allergic skin reactions, anaphylaxis) may occasionally occur. If allergic reactions occur, the product should be discontinued immediately. Appropriate symptomatic treatment should be initiated.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))

- common (more than 1 but less than 10 animals in 100 animals treated)

- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)

- rare (more than 1 but less than 10 animals in 10,000 animals treated)

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

7. TARGET SPECIES

Cattle, pigs, dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Cattle, pigs, dogs and cats: 8.75 mg/kg bodyweight, equivalent to 1 ml/20 kg bodyweight. Treatment should be administered once daily for 3 to 5 days.

Dogs and cats: subcutaneous or intramuscular injection.

Cattle and pigs: intramuscular injection only .

Combined therapy for the treatment of bovine mastitis: in the situation where systemic as well as intramammary treatment is necessary, Synulox Ready-to-Use Injection can be used in combination with Synulox Lactating Cow Intramammary.

For combined therapy the following minimum treatment regime should be followed:

Synulox RTU	Synulox LC
8.75 mg/kg bodyweight (7.0 mg amoxicillin, 1.75 mg clavulanic acid) i.e. 1 ml/20 kg bodyweight ↓ 24 hours 8.75 mg/kg bodyweight (7.0 mg amoxicillin, 1.75 mg clavulanic acid) i.e. 1 ml/20 kg bodyweight ↓ 24 hours 8.75 mg/kg bodyweight (7.0 mg amoxicillin, 1.75 mg clavulanic acid) i.e. 1 ml/20 kg bodyweight Where necessary, Synulox RTU Injection may be administered for an additional two days for a total of 5 daily injections	One syringe gently infused into the teat of the infected quarter ↓ 12 hours One syringe gently infused into the teat of the infected quarter ↓ 12 hours One syringe gently infused into the teat of the infected quarter

9. ADVICE ON CORRECT ADMINISTRATION

Shake the vial to suspend the active material. Massage the injection site.

10. WITHDRAWAL PERIOD(S)

Milk for human consumption must not be taken during treatment. Milk for human consumption may only be taken from cattle at 60 hours (5th milking, if cows are milked twice daily).

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only 42 days from the date of last treatment. Pigs may be slaughtered for human consumption only 31 days from the date of last treatment.

Combined therapy: when using Synulox RTU and Synulox LC Intramammary in combination, animals must not be slaughtered for human consumption during treatment. Cows may not be slaughtered for human consumption until 42 days after the last treatment. Milk must not be taken for human consumption during treatment. Milk for human consumption may be taken only from cows after 60 hours from the last treatment of Synulox RTU.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C. Keep out of the sight and reach of children.

Shake the vial well before use. Swab the septum before removing each dose. Use a completely dry sterile needle and syringe.

This product does not contain antimicrobial preservative. Following withdrawal of the first dose, use the product within 28 days.

When the container is broached for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

Clavulanic acid is moisture sensitive. It is very important, therefore, that a **completely dry syringe** is used when extracting suspension for injection in order to avoid contaminating the remaining contents of the vial with drops of water. Contamination will result in obvious areas of dark brown discolouration corresponding to the introduced water droplets. Material affected in this way should not be used as it may have significantly reduced potency.

The product may contain minute brown spots, which are considered to be an intrinsic characteristic of the formulation. Appearance of these spots will not adversely affect the safety or efficacy of the product.

12. SPECIAL WARNING(S)

For animal treatment only.

Operator Warnings

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations. Handle this product with great care to avoid exposure, taking all recommended precautions.

If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention. Wash hands after use.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

15. OTHER INFORMATION

Synulox Ready-To-Use Injection is available in cartons containing 1 x 40 ml or 12 x 40 ml, and 1 x 100 ml or 6 x 100 ml vials. Not all pack sizes may be marketed.

POM-V

Vm 60021/3021

PRODUCT SUMMARY

• **Novel Formulation** - dual action of clavulanate-potentiated amoxicillin.

• **Extended Spectrum of Activity** - clavulanate extends the spectrum of amoxicillin by making it active against resistant (ß-lactamase-producing) strains of staphylococci, *E. coli*, salmonellae and *Campylobacter* species. Furthermore Klebsiella species are added to the range of susceptible organisms.

• **Kills Bacteria Rapidly** - increases the likelihood of a rapid clinical cure.

• **Excellent Absorption and Penetration** - ensures sufficiently high levels of Synulox at the common infection sites to achieve clinical success.

• **Highly Effective** - the novel formulation of Synulox increases the high cure rates achieved with amoxicillin alone.

Resistance to many antibiotics is caused by ß-lactamase enzymes which destroy the antibiotic before it can act on the bacteria themselves. The clavulanate in Synulox counter-acts this defence mechanism by inactivating the ß-lactamases, thus rendering the bacteria sensitive to amoxicillin's rapid bactericidal effect, at concentrations readily attainable in the body.

Synulox is effective against Klebsiella infections found in veterinary practice, but it is not indicated for cases involving Pseudomonas species.

Gavin Hall

Approved 15 November 2024